



Presidential Commission for the Study of Bioethical Issues

Medical Countermeasure Distribution November 5, 2012

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“Protect, Prevent, Live Well”



Introduction

- Thank you for this opportunity to provide comments on medical countermeasure distribution in a public health emergency
- I am here in my capacity at APHA; Not in my capacity with the National Biodefense Science Board or any other federal capacity



Medical Countermeasures Are Used To Treat or Prevent

- Weapons of mass destruction
 - Chemical, biological, radiological, and nuclear (CBRN) agents
- Emerging infectious diseases with high casualty potential
 - Pandemic flu, SARS etc.
- Includes medicine, devices & other medical interventions

High Priority Threats

- **Bacillus anthracis (anthrax)***
- **Clostridium botulinum toxin (botulism)***
- **Cyanide**
- **Emerging infectious diseases (including pandemic influenza)**
- **Gram negative organisms**
 - **Francisella tularensis (tularemia)**
 - **Yersinia pestis (plague)**
 - **Burkholderia mallei (glanders) and B. pseudomallei (melioidosis)**
 - **Rickettsia prowazekii (typhus)**
- **Multi-drug resistant Bacillus anthracis (MDR anthrax)**
- **Nerve agents**
- **Radiological agents (e.g., radiological dispersal devices)**
- **Nuclear agents**
- **Variola virus (smallpox)***
- **Viral Hemorrhagic Fevers**
 - **Marburg**
 - **Ebola**



HHS 2012 PHEMCE Strategy

Goal 1 - Identify, create, develop, manufacture, and procure critical medical countermeasures

Goal 2 - Establish and communicate clear regulatory pathways to facilitate medical countermeasure development and use

Goal 3 - Develop logistics and operational plans for optimized use of medical countermeasures at all levels of response*

Goal 4 - Address medical countermeasure gaps for all sectors of the American civilian population*

1st Plan 2007 & Updated Every 5 years



PHEMCE Implementation Plan

- Address the most significant threats
- Foster approaches that address protection against multiple threats
- Maintain the capability to effectively use these assets in the operational setting

Central Challenge Is Distribution

All states have a MCM distribution plan as a component of their preparedness plans

- First response is local
- States & locals preparedness plans to distribute countermeasures have a general assumption of 72 hours “on their own” recognizing federal support for medical countermeasures can get there within 12 hours



Strategic National Stockpile (SNS)

- Forward placed caches of 12 Hour push packs of pharmaceuticals, vaccines, antiviral drugs & medical supplies & equipment
- **SNS** managed & **Vendor** managed assets
- All states have a plan to received the SNS that have been tested & evaluated



MCM Dispensing Strategies

- Health provider / pharmacy dispensing
- Health department delivery or dispensing
- Forward deployed MCM (SNS)
- Cached MCM
- Predispensed medical counter measures
- U.S. Postal Service delivery model



Dispensing Systems Are Complex

- Authorizing
- Filling the therapeutic
- Large volume - Dispensing or delivery (e.g. vaccines)
- Documentation
- Complications surveillance
- Ensuring compliance



Specific Challenges For Children

- Parental consent & custody issues
- Child / parent separation (school, child care)
- Dosage variation from adults
- Supply of medications
- Allergies, contraindications, or complications
- IND, EUA & off label use for kids
- Inclusion in response exercises

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